This 510(k) summary is being submitted in accordance with 21 CFR § 807.92.

General Information

Establishment

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Mail Code D02
Malvern, PA 19355, USA
Registration Number 2240869

Manufacturer

Siemens AG
Henkestrasse 127
D-91052 Erlangen, Germany
Registration Number 3002808157

SIEMENS SHENZHEN MAGNETIC RESONANCE LTD.
Siemens MRI Center
Hi-Tech Industrial park (middle)
Gaoxin C. Ave., 2nd
Shenzhen 518057, P.R. CHINA
Registration Number 3004754211

Contact Person

Ms. Nadia Sookdeo
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Mail Code D02
Malvern, PA 19355, USA
Phone: (610) 448-4918
E-mail: Nadia.Sookdeo@siemens.com

Device Name

Software update syngo MR D13A-AP-AA to the commercially available software version syngo MR D13A for MAGNETOM Aera and MAGNETOM Skyra

CFR Code

21 CFR § 892.1000

Classification

Class II

Product Codes

LNH, LNI, MOS

Classification Name

Magnetic Resonance Diagnostic Device, MR Spectroscopy, MR Coils

Information Supporting Substantial Equivalence

DEVICE DESCRIPTION

The software version *syngo* MR D13A is updated for two Siemens MR systems:

- MAGNETOM Aera (1.5T)
- MAGNETOM Skyra (3T)

Systems that are already in clinical use and at customer sites can be updated with this software update; both MAGNETOM systems can be manufactured with this software update.

This software update includes modified software sequences for MAGNETOM Aera and MAGNETOM Skyra.

MAGNETOM Aera and MAGNETOM Skyra with software *syngo* MR D13A were previously cleared under K121434 (November 5, 2012).

Summary of Features New with the Software Update compared to the commercially available Software Version *syngo* MR D13A:

Software

- Modified sequences:
  - Quiet sequences
  - VIBE sequence improvements

INTENDED USE

The MAGNETOM systems Aera and Skyra with the updated software *syngo* MR D13A are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

The MAGNETOM systems Aera and Skyra with the updated software *syngo* MR D13A may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.

NONCLINICAL TESTS

Performance testing such as acoustic noise testing was conducted on the subject device. Additionally, all software features were verified and validated.

The results from each set of tests demonstrate that the device performs as intended and is thus substantially equivalent to the predicate devices to which it has been compared.

CLINICAL TESTS

There were not any clinical tests conducted to support the subject device and the substantial equivalence argument, however clinical images are provided to support the modified software features of the subject device.

SUBSTANTIAL EQUIVALENCE

Software update to the commercially available software version *syngo* MR D13A for MAGNETOM Aera and MAGNETOM Skyra is substantially equivalent to the following predicate devices:

Predicate Device Name	FDA Clearance Number	FDA Clearance Date	Main Product Code
MAGNETOM Aera, Skyra, Avanto, and Verio with *syngo*® MR D13A	K121434	November 5, 2012	LNH

Table 1 Predicate device for Software Update to the commercially available software version syngo MR D13A for MAGNETOM Aera and MAGNETOM Skyra

SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions USA, Inc. and Siemens AG adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.

MAGNETOM systems Aera and Skyra with the updated software *syngo* MR D13A conform to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

SUBSTANTIAL EQUIVALENCE CONCLUSION

There are no changes to the Indications for Use for the subject device, compared to that of the predicate MAGNETOM scanners with software *syngo* MR D13A.

While the updated software provides the user with additional capabilities compared to the two subject MAGNETOM systems with the previous software version *syngo* MR D13A, it has the same technological characteristics as that of the predicate devices. The modifications of the updated software version make the systems and software more user- and patient-friendly – providing imaging techniques with lower noise towards the patient; improving the user's workflow; providing additional information and options to the user.

The differences between the subject device and the predicate devices, which include the aforementioned modified sequences, give the systems greater capabilities than the predicate devices, but have the same technological characteristics as the predicate devices, are similar to the functionalities of the predicate devices, and do not introduce any new issues of safety or effectiveness.

Therefore, Siemens believes that the subject device, the updated software version *syngo* MR D13A for MAGNETOM systems Aera and Skyra is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 1, 2013

Siemens Medical Solutions USA, Inc.
% Ms. Nadia Sookdeo
Regulatory Affairs Technical Specialist
51 Valley Stream Parkway, MC D02
MALVERN PA 19355

Re: K132831
Trade/Device Name: Syngo MR D13A-AP-AA software update
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: September 25, 2013
Received: September 26, 2013

Dear Ms. Sookdeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132831

Device Name: Syngo MR D13A-AP-AA software update for MAGNETOM Aera and MAGNETOM Skyra

Indications for Use:

The MAGNETOM systems Aera and Skyra with the updated software syngo MR D13A are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

The MAGNETOM systems Aera and Skyra with the updated software syngo MR D13A may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K132831